



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,020	12/19/2001	Esha A. Gangolli	21402-225 (Cura-525)	3246

7590 12/30/2005

Ivor R. Elrifi
Mintz, levin, Cohn, Ferris, Glovsky and Popeo, P.C
One Financial Center
Boston, MA 02111

EXAMINER

MITRA, RITA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,020	GANGOLLI, ESHA A.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,9,12-14,39,42 and 50-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,9,12-14,39,42 and 50-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The request filed on October 31, 2005 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/029020 is acceptable and an RCE has been established. An action on the RCE follows.

Status of the Claims

Applicants' Amendment and Response to Office Action mailed June 30, 2005, filed on October, 2005 is acknowledged. Claims 1-4, 6-8, 10-11, 15-38, 40-41 and 43-49 have been canceled. Claims 5, 9, 51, 52, 53, 55, 57-59 have been amended. New claims 60, 61 have been added. Therefore, claims 5, 9, 12-14, 39, 42 and 50-61 are currently under examination.

Response to Amendments and Remarks

Claim Rejections- 35 USC § 112, first paragraph

Rejection of claims 5, 9 under 35 USC 112, first paragraph written description is withdrawn in view of amendment to claims.

Claim Rejections- 35 USC § 102

Rejection of claims 5, 12-14, 39, 42 and 50-53 under 35 USC 102 is withdrawn in view of amendment to claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title”

Art Unit: 1653

Claims 5, 9, 12-14, 39, 42 and 50-61 stand/ are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed nucleic acids are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed nucleic acids or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed nucleic acids or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed. The reasons were given in the previous office actions.

The rejection has been set forth in the previous office actions. In response, Applicants traverse the foregoing rejection and argue (pages 5-6), that the nucleic acids of the claimed invention are useful as cancer markers by detecting the level of expression of these specific nucleic acids in a tissue sample from tumor and comparing the expression level in the corresponding normal tissue, thus as Applicants assert the utility of the claimed nucleic acids is specific, rather than generally applicable to broad classes of nucleic acids. In response it should be noted that the claimed nucleic acid has a specific sequence structure but the disclosed uses are not specific for the claimed nucleic acids. Further Applicants argue that the skilled artisan would appreciate that the measurement of the relative level of expression of nucleic acid is useful as a real-world tool in cancer diagnosis. The arguments are not persuasive because it should be noted that the claimed subject matter is not supported by a specific utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use.

As for the differential expression of certain genes in a variety of different cancer, Applicants have stated that consistent misexpression of a gene in different cancer types increases the gene's value as a diagnostic tools. However, the specification fails to provide any evidence to support this assertion that the claimed gene (Gene CG50301-01, page 229) of the invention would be considered for such a diagnostic tool. Therefore, identifying and studying the

Art Unit: 1653

properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a “real world” context of use. The specification fails to provide any activity or function of this gene. Therefore, one skilled in the art should not have to engage in discovering genomics to learn how to use the invention. This situation requires carrying out future additional research to identify or reasonably confirm a “real world” context of use and therefore do not define specific and substantial utility. Therefore, the rejection under 35 U.S.C. 101 remains.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 9, 12-14, 39, 42 and 50-61 stand/are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claims 51-53 and 57-61 stand/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 51-53 and 57-61 stand/are directed to polynucleotide variants of the sequence of SEQ ID NO: 13 encoding the polypeptide of SEQ ID NO: 14. As discussed above, based on the specification (pages 10-12, 48-67, Table 14 at page 294) it is unclear what activity the claimed variants possess, what activity the encoded proteins possess and therefore unclear how a person having skill in the art would have used the claimed variants. The specification does not describe the functional properties of these variants, and the structural information is limited. Therefore,

Art Unit: 1653

how a skilled artisan would know how to use the claimed variants without undue experimentation.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 61 is rejected under 35 USC 102(b) as being anticipated by Oohashi et al. (“Mouse Ten-m/Odz is a new family of dimeric type II transmembrane proteins expressed in many tissues,” The J. of Cell Biology, vol 145, No. 3, pp 563-577, May 3, 1999). Oohashi et al. teach a protein that lacks signal peptide but contains a hydrophobic domain after 300-400 amino acids from N-terminus and contain 8 consecutive EGF-like domain to the C-terminal of the hydrophobic domain (see abstract). Oohashi’s protein having 97.6% sequence identity to SEQ ID NO: 14 (see alignment result 1, Oohashi et al., “Ten-m4”, November 1, 1999, Accession NO: Q9WTS7_MOUSE, Database: UniProt_05.80) is considered for the variant having at least 97% sequence identity to SEQ ID NO: 14 of claim 61.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Dr. Jon Weber can be reached on 571-

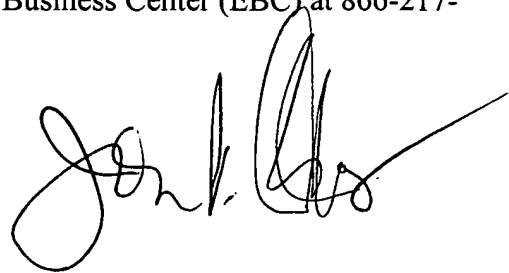
Art Unit: 1653

272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

December 23, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER